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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631
7590 Lisa E. Alexander Sagres Discovery, Inc. c/o Chiron Corporation P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 11/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,920

Applicant(s)

MORRIS ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61,67,69-72 and 74-90 is/are pending in the application.
4a) Of the above claim(s) 82-84 is/are withdrawn from consideration.
5) ☒ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 61,67,69-72,74-81 and 85-90 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 61, 67, 69-72 and 74-90 are pending.
Claims 85-90 have been added.
Claims 61, 74 and 81 have been amended.
Claims 82-84, drawn to non-elected inventions are withdrawn from examination.
Claims 61, 67, 69-72 and 74-90 are examined on the merits.
2. Applicants addition of new claims 85-90 are not regarded as new matter.
Support for these limitations are found in the specification, page 72, section 0175- page 75, section 0181 and page 108, section 289-page 109, section 291.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

3. The rejection of claims 61, 67, 69-72 and 74-81 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing lymphoma, carcinoma, breast cancer or colon cancer comprising detecting evidence of differential expression of complement receptor type 1 (CR1) gene in a patient sample, wherein evidence of differential expression is detected by measuring the level of an expression product of CR1 and wherein the expression product is a mRNA having a sequence of SEQ ID NO: 1320, wherein evidence of differential expression of the CR1 gene indicates that the patient has lymphoma, carcinoma, breast cancer or colon

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cancer, does not reasonably provide enablement for the said method measuring a full complement of the mRNA sequence of SEQ ID NO: 1320 (CR1) is withdrawn in light of the claim amendments made to claims 61 and 81.

New Objection

Claim Objections

4. Claim 67 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 67 includes the broad term, cancer while depending from claim 61 that cites specific and limiting cancer types.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 87-89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 87 is vague and indefinite in the recitation "...hybridizes under highly stringent conditions...". While a suggested example of hybridization conditions is

provided on page 38 of the specification this example is not non-limiting and the metes and bounds of the hybridization conditions are not clear.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0110792 A1 (filed October 20, 2002). The publication discloses a method of analyzing gene expression profiles of a patient with acute myelogenous leukemia (AML) and assessing said leukemia, see title and abstract. The publication cites a method wherein PCR and array hybridization are implemented and differential expression of target genes are assessed for up regulation, as well as down regulation between diseased cells, untreated diseased cells and a control sample, see section 0030 bridging pages 2 and 3; page 3, section 0031; page 7, sections 0039-0043; and Example 6, section 0069 on page 7. Sequence 293 from the publication is a nucleotide, which shares sequence homology with Applicants' SEQ ID

NO: 1320. The said nucleotide is able to form a duplex when contacted with the probes used in the taught assays, see attached database sheet.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 87-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2004/0110792 A1 (filed October 20, 2002). The publication teaches a method of analyzing gene expression profiles of a patient with acute myelogenous leukemia (AML) and assessing said leukemia, see title and abstract. The publication cites a method wherein PCR and array hybridization are implemented and differential expression of target genes are assessed for up regulation, as well as down regulation between diseased cells, untreated diseased cells and a control sample, see section 0030 bridging pages 2 and 3; page 3, section 0031; page 7, sections 0039-0043; and Example 6, section 0069 on page 7. Sequence 293 from the publication is a nucleotide, which shares sequence homology with Applicants' SEQ ID NO: 1320. The said nucleotide is able to form a duplex when contacted with the probes used in the taught assays, see attached database sheet. The publication does not teach the method, wherein the precise hybridization conditions set forth in claim 90 are used.

However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to implement the teachings of the patent application in order to effectively diagnose leukemia using the methodology cited therein using the hybridization criteria set forth in the claims. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the listed teachings in the patent application publication that the method implementing a range of washes and stringencies is routine in experimentation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 61, 67, 69-72, 74-81 and 85-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of copending Application No. 10/573,332 (filed April 6, 2007).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims read on diagnosing cancer comprising determining the expression of a gene with the sequence, SEQ ID NO: 1320 (complement receptor type 1/ CR1), see database sheet alignment and Tables 1-124 of '332 application.

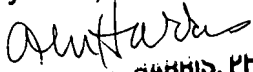
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
01 November 2007